

REMARKS/ARGUMENTS

Applicants gratefully acknowledge the courtesy shown by Examiner Fronda and Supervisory Patent Examiner Achutamurthy during the telephone interview with J. Scott Elmer, Director of Technology Licensing for the assignee St. Jude Children's Research Hospital, Paul Fehlner of Darby & Darby, and the undersigned on January 19, 2006. During the interview, the claim rejections for lack of enablement under 35 U.S.C. § 112, first paragraph were discussed. This Amendment cancels claims, adopts the Examiner's suggestions, and is believed to be in accordance with the understanding reached with the Examiner in the interview.

Status of the claims

Claims 1-10, 13-20 and 22-35 are pending. Claims 1-8, 11, 12, 18 and 21-33 have been canceled without prejudice to pursue them in one or more divisional or continuation applications. New claims 34 and 35 have been added. Claim 9 has been amended to recite that the isolated nucleic acid encodes an Ozz protein, which shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2 or SEQ ID NO:4. Claim 15 has been amended to recite that full-length Ozz protein shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2 or SEQ ID NO:4. Support for these amendments can be found in the specification at page 7, lines 20-23 and page 38, lines 21-25. Claim 17 has been amended to recite "an isolated host cell" in accordance with the Examiner's suggestion. Claim 20 has been amended to recite that the isolated nucleic acid hybridizes under specified stringent conditions "with a nucleic acid having a nucleotide sequence depicted in SEQ ID NO:1 or SEQ ID NO:3." Support for this amendment can be found in the specification at page 2, line 30 to page 3, line 2; and original claim 20. Support for new claims 34 and 35 can be found in the specification at, for example, page 2, lines 12-14, and original claims 11 and 12.

SEQ ID NO:4 has been added to claim 9 because SEQ ID NOS:2 and 4 are related to each other by the recited structural characteristics (90% sequence identity, 92% sequence similarity). Claim 9 thus defines a genus that includes both SEQ ID NOS:2 and 4. Similarly, SEQ ID NO:3 has been added to claim 20 to define a genus that includes SEQ ID NOS: 1 and 3.

The objection to claim 14

Claim 14 has been objected to as being dependent upon a rejected base claim. Claim 14 depends from claim 13. Claim 13 depends from claim 9. As explained below, the rejections of claims 9 and 13 should be withdrawn. Accordingly, the objection to claim 14 should also be withdrawn.

The rejection of claims 9-10, 13, 15-17, 19 and 20 under 35 U.S.C. § 112, first paragraph, enablement

Claims 9-10, 13, 15-17, 19 and 20 stand rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. The Examiner contends that “an undue amount to trial and error experimentation must be performed to search and screen for the specific nucleotides to change ... that will result [in] an isolated nucleic acid encoding a functional Ozz protein that shares about 90%-92% sequence similarity with SEQ ID NO:2” (Office Action, page 3).

This rejection should be withdrawn because Ozz is a novel nucleic acid and protein with a tissue-specific expression (Ozz is “characterized by a tissue-specific expression pattern. Both Ozz mRNA and Ozz protein are only observed in heart and skeletal muscle...” specification, page 8, lines 1-5). Claim 9 specifically states that the nucleic acid is expressed only in cardiac and skeletal muscle. Nature, in the course of evolution, has “performed [the] search and screen” that will result in the claimed Ozz nucleic acids because they are found in cardiac and skeletal muscle. Isolating, sequencing, and characterizing the sequence relationship to SEQ ID NOS:2 or 4 requires less than routine skill in the art. Accordingly, there is no need for undue experimentation by one of ordinary skill in the art.

Applicant notes that the claims 9-10, 13, 15-17, and 19 include the limitation “about 90% sequence identity or about 92% sequence similarity,” and not “about 90%-92% sequence similarity” as recited in the Office Action at pages 2-3.

For the reasons stated above, this rejection should be withdrawn.

The rejection of claim 20 under 35 U.S.C. § 112, first paragraph, enablement

The examiner has maintained the rejection of claim 20 under 35 U.S.C. § 112, first paragraph, enablement. According to the examiner, “no guidance or prediction” is provided regarding “the specific hybridization conditions that would effectively screen out any hybridization

to any region of the PPCA exon Ia.” The examiner contends that it would require undue experimentation to determine the hybridization conditions that would not result in the claimed nucleic acid hybridizing to any region of the PPCA exon Ia.

This rejection is not directed to the subject matter as claimed. Claim 20 is directed to an isolated nucleic acid consisting of at least ten consecutive nucleotides of SEQ ID NO:1 that hybridizes under specified stringent conditions with the nucleotide sequence depicted in SEQ ID NO:1, with the simple proviso that the claimed isolated nucleic acid is not PPCA exon Ia. To avoid anticipation by the prior art, the claim excludes this species. One of ordinary skill in the art could easily determine, from a synthetic protocol or by routine sequencing, whether the sequence of a nucleic acid that hybridizes under the recited conditions to the nucleotide sequence of SEQ ID NO:1 is the PPCA exon Ia. A nucleic acid sequence that does not correspond to the sequence of this exon is covered under the claim. All that is required of the skilled artisan is to recognize the PPCA exon 1 and exclude it. No determination of hybridization conditions is required.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By  _____

Paul M. Zagar
Registration No.: 52,392
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant